

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO
**INFORMATION DISCLOSURE
 STATEMENT BY APPLICANT**

Date Submitted: December 11, 2003

(use as many sheets as necessary)

Complete if Known

Application Number	10/667,472
Filing Date	09/23/2003
First Named Inventor	Ray W. Wood
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	029318-0976

Sheet **P E** 1 of 3

U.S. PATENT DOCUMENTS

Examiner Initials* TRADEMARK OFFICE No. 1	U.S. Patent Document Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
M	A1	5,145,684	LIVERSIDGE ET AL.	09/1992	
	A2	5,091,187	HAYNES	02/1992	
	A3	5,091,188	HAYNES	02/1992	
	A4	4,807,814	Douche <i>et al.</i>	02/28/1989	
	A5	4,826,821	Clements	05/02/1989	
	A6	5,118,528	Fessi <i>et al.</i>	06/02/1992	
	A7	5,202,110	Dalby <i>et al.</i>	04/13/1993	
	A8	5,225,183	Purewal <i>et al.</i>	07/06/1993	
	A9	5,260,478	Bacon <i>et al.</i>	11/09/1993	
	A10	5,264,610	Bacon	11/23/1993	
	A11	5,300,739	Bittar	04/05/1994	
	A12	5,322,679	Bacon <i>et al.</i>	06/21/1994	
	A13	5,518,738	Eickhoff <i>et al.</i>	05/21/1996	
	A14	5,747,001	Wiedmann <i>et al.</i>	05/05/1998	
	A15	5,785,049	Smith <i>et al.</i>	07/28/1998	
	A16	5,985,309	Edwards <i>et al.</i>	11/16/1999	
	A17	5,264,213	Shibahara <i>et al.</i>	11/23/1993	
	A18	5,098,907	Kondo <i>et al.</i>	03/24/1992	
	A19	5,002,952	Kondo <i>et al.</i>	03/26/1991	
	A20	4,983,605	Kondo <i>et al.</i>	01/08/1991	
	A21	4,904,668	Kondo <i>et al.</i>	02/27/1990	
	A22	4,851,421	Iwasaki <i>et al.</i>	07/25/1989	
	A23	4,727,077	Haga <i>et al.</i>	02/23/1988	
M	A24	4,540,602	Motoyama <i>et al.</i>	09/10/1985	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
M	A25	WO	02/098565	A1	ELAN PHARMA INTERNATIONAL LIMITED	12/12/2002		
M	A26	WO	92/08446	A1	GLAXO GROUP LIMITED	05/29/1992		
M	A27	EP	0 602 702	A1		12/1993		
M	A28	GB	2 237 510	A		05/1991		

Examiner
Signature

Date
Considered

9/21/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO
**INFORMATION DISCLOSURE
 STATEMENT BY APPLICANT**

Date Submitted: December 11, 2003

(use as many sheets as necessary)

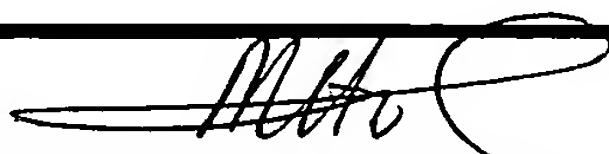
Complete if Known

Application Number	10/667,472
Filing Date	09/23/2003
First Named Inventor	Ray W. Wood
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	029318-0976

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	Office ³	Number ⁴	Kind Code ⁵ (if known)				
M	A29	WO	91/16038		10/1991		
	A30	DE	43 27 063	A1	02/1995		
	A31	WO	94/20072		09/1994		
	A32	WO	95/27475		10/19/1995		
	A33	WO	96/25918		08/29/1996		
	A34	WO	98/35666		08/20/1998		
	A35	WO	99/30687		06/24/1999		
	A36	WO	99/38493		08/05/1999		
	A37	WO	99/45779		09/16/1999		
	A38	EP	0 275 796		07/27/1998		
M	A39	EP	0 347 779		12/27/1989		
	A40	EP	0 499 299	A2	08/19/1992		
	A41	EP	0 262 560		04/06/1998		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
M	A42	Stephen P. Newman, Chapter 9, "Therapeutic Aerosols," in Aerosols and the Lung, Clarke et al., eds., pp. 197-224 (Butterworths, London, England, 1984)	
	A43	Prodi et al., "Airborne Particles And Their Intrapulmonary Deposition", in Scientific Foundations Of Respiratory Medicine, J. G. Scadding ed., pp. 545-558 (W.B. Saunders Co., Philadelphia, PA 1981)	
	A44	J. Heyder, "Mechanisms Of Aerosol Particle Deposition", Lung Mucociliary Clearance, 80(6):820-823 (1981)	
	A45	Fox et al., "Performance Of A Venturi Eductor As A Feeder In A Pneumatic Conveying System," Powder And Bulk Engineering, pp. 33-36 (1988)	
	A46	Tiano, "Functionality Testing Used To Rationally Assess Performance Of A Model Respiratory Solution Or Suspension In A Nebulizer (Performance Assessment)," Vol. 56/12-B of Dissertation Abstracts International (1995)	
M	A47	Waldrep et al., "Operating Characteristics of 18 Different Continuous-Flow Jet Nebulizer With Beclomethasone Dipropionate Liposome Aerosol," Chest, 105(6):106 (1994)	
	A48	P. Byron, "Aerosol Formulation, Generation, And Delivery Using Nonmetered Systems," Respiratory Drug Delivery, 144-151 (CRC Press, 1989)	

Examiner Signature



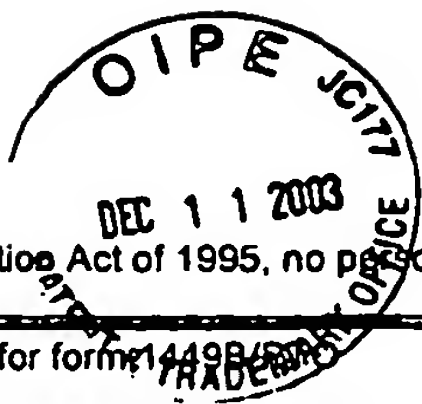
Date Considered

9/21/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/08-00		Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/667,472
Date Submitted: December 11, 2003		Filing Date	09/23/2003
(use as many sheets as necessary)		First Named Inventor	Ray W. Wood
		Group Art Unit	Unassigned
		Examiner Name	Unassigned
		Attorney Docket Number	029318-0976
Sheet	3	of	3

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
M	A49	Soviet Union Patent No. 628930, for "Bulb-Actuated Ejector For Powdered Medicinal Substance" (1978)	
	A50	F. Moren, Chapter 13, "Aerosol Dosage Forms and Formulations," Aerosols in Medicine. Principles, Diagnosis and Therapy, 2nd Edition, F. Moren et al. eds. (Elsevier Science Publishers 1993)	
	A51	Remington's Pharmaceutical Sciences, pp. 1565-1567 (Mack Publishing Company 1990)	
	A52	Edwards et al., "Large Porous Particles for Pulmonary Drug Delivery," Science, 276:1868-1871 (June 20, 1997)	
M	A53	"Test Method B527-93(2000)el Standard Test Method for Determination of Tap Density of Metallic Powders and Compounds," http://www.astm.org/DATABASE.CART/PAGES/B527.htm	
	A54	"Autotap and Dual Autotap," http://www.quantachrome.com/Density/Autotap.htm	
	A55	"Optimal Tapped Density Tester," http://optimalcontrol.com/tapped.html	
M	A56	N. Kondo et al, "Improved Oral Absorption of a Poorly Water-Soluble Drug, HO-221, by Wet-Bead Milling Producing Particles in Submicron Region," <u>Chem. Pharm. Bull.</u> , 41(4), pgs. 737-740, 1993.	
	A57	N. Kondo et al, "Pharmacokinetics of a Micronized, Poorly Water-Soluble Drug, HO-221, in Experimental Animals," <u>Chem. Pharm. Bull.</u> , 16(8), pgs. 796-800, 1993.	
M	A58	N. Kondo et al, "Improved Oral Absorption of Enteric Coprecipitates of a Poorly Soluble Drug," <u>Journal of Pharmaceutical Sciences</u> , 83(4), pgs. 566-570, © American Chemical Society and American Pharmaceutical Association, 1993.	

Examiner Signature		Date Considered	9/21/05
--------------------	--	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

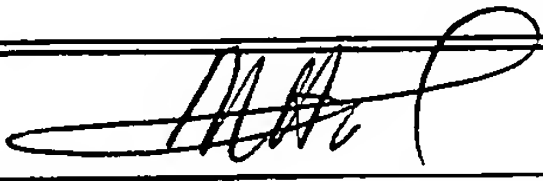
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/667,472
			Filing Date	09/23/2003
			First Named Inventor	Ray W. Wood
			Group Art Unit	1616
			Examiner Name	Unassigned
Sheet 1 of 1			Attorney Docket Number	029318-0976

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Office ³	Number ⁴	Kind Code ⁵ (if known)			
M	A1	WO	92/18105	A1	SANDOZ LTD.	10/29/1992	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
M	A2	KIRBY ET AL., "Liposomes," <i>Encyclopedia of Controlled Drug Delivery</i> , Vol. 1, John Wiley & Sons, 1999, pp. 461-473.	
	A3	VOIGHT, <i>Pharmazeutische Technologie</i> , 7 th Edition, Ullstein Mosby, 1993, pp. 181-182.	
	A4	STRICKER (Ed.), <i>Physikalische Pharmazie</i> , 3 rd Edition, Wissenschaftliche Verlagsgesellschaft Stuttgart, 1987, pp. 27-28.	
M	A5	CRAIG ET AL., "The relevance of the amorphous state to pharmaceutical dosage forms: glassy drugs and freeze dried systems," <i>International Journal of Pharmaceutics</i> , 179(1999), pp. 179-207.	

Examiner Signature		Date Considered	9/21/05
--------------------	--	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.